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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/643,260	08/22/2000	Michael J. May	044574-5066-US	9021

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EXAMINER
MITRA, RITA

ART UNIT	PAPER NUMBER
1653	7

DATE MAILED: 06/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No. 09/643,260	Applicant(s) MAY ET AL.	
	Examiner Rita Mitra	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to a method of inhibiting NF-kB induction in a cell by administering a peptide which blocks the interaction of one or more IKKs and NEMO, classified in class 514, subclass 2.

Should Group I be elected, applicants are required to select one sequence of peptides of SEQ ID NOs: 2, 4-6, 11-12, 16-17.

II. Claims 6-9, drawn to a method of inhibiting inflammation in a mammal by administering a peptide which blocks the interaction of IKK and NEMO, classified in class 514, subclass 2.

III. Claims 10-12, drawn to a method of inhibiting NF-kB dependent target gene expression in a cell by administering a peptide which blocks the interaction of IKK and NEMO, classified in class 514, subclass 2.

IV. Claim 13, drawn to a method for the identification of an agent that interacts with the NEMO binding domain, classified in class 435, subclass 7.1.

V. Claim 14, drawn to a method for identifying an agent which modulates the activity of NEMO, classified in class 435, subclass 7.95.

VI. Claims 15-18, 20 and 21 drawn to a fusion peptide comprising the NEMO binding domain and at least one membrane translocation domain, and a composition comprising the said fusion peptide, wherein the NEMO binding domain is selected from the group consisting of SEQ ID NO: 2-17, classified in Class 530, subclasses 324 and 329; class 435, subclass 69.7

Should Group VI be elected, applicants are required to select one sequence of peptides of SEQ ID NOs: 2-17.

VII. Claims 19, 20, 21 and 22, drawn to an isolated peptide and fragments or variants thereof, and a composition comprising the said peptide, comprising or related to SEQ ID NOs: 2-19, classified in class 530, subclass 324 and 329; class 514, subclass 2.

Should Group VII be elected, applicants are required to select one sequence of peptides of SEQ ID NOs: 2-19.

VIII. Claim 23, drawn to an isolated nucleic acid molecule that encodes the amino acid sequence of SEQ ID NOs: 2-19, and fragments thereof, classified in class 536, subclass 23.5.

Should Group VIII be elected, applicants are required to select one sequence of peptides of SEQ ID NOs: 2-19.

The inventions are distinct, each from the other because of the following reasons:

The methods of inventions I-III are related by virtue of the peptide which is used in the methods. The inventions are distinct, each from the other, because they require different steps and are directed to different outcomes. Therefore, the inventions are patentably distinct.

Inventions I, II, III and IV, V are unrelated. The inhibition methods of groups I, II, III and the methods of identification of groups IV, V are not disclosed as capable of use together

and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). Therefore, the inventions are distinct.

The methods of inventions IV and V are related by virtue of the peptide which is used in the methods. The inventions are distinct, each from the other, because they are directed to different outcomes and the identification of compounds having separable and materially distinct activities and different functions. Therefore, the inventions are patentably distinct.

Groups VI, VII, and VIII are different products. Peptides and nucleic acids differ with respect to their structures and physicochemical properties, therefore each product is patentably distinct.

The nucleic acid of group VIII is related to the protein of group VI, VII by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays. Therefore, the inventions are distinct.

Inventions VI, VII and I-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the peptide of groups VI and VII can be used for the generation of antibodies specific for the peptide. Therefore, the inventions are distinct.

Inventions VIII and I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the

nucleic acid of group VIII is not used in the methods of groups I-V. Therefore, the inventions are distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Attorney Maria Laccotripe on June 5, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to

Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rita Mitra, Ph.D.
June 7, 2002

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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